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<p>(54) Title: DOSE SETTING DEVICE</p> <p>(57) Abstract</p> <p>By a dose setting device for a delivery system wherein a piston rod (6, 9) successively presses a piston (2) into a cylinder ampoule (1) a dose is set by rotating a second part (9) of the piston rod (6, 9) in relation to a first part (6) which parts are connected by mating threads so that the total length of the piston rod (6, 9) is increased proportionally with the rotation and a point (18) on the second part is moved away from a stop position fixed in relation to a housing (5). The set dose is delivered when said point (18) is moved back to the stop position. The first part (6) can be axially displaced but not rotated in the housing (5), and the second part (9) can be as well rotated as axially displaced. The first part (6) is maintained in abutment with the piston (2) and the second part (9) is coupled to be rotated by a dose setting wheel (20). An injection push button (10) is movable between a projecting position and a pressed home position and has elements (13) acting on the second part (9) to press this part to its stop position.</p>			

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**Dose Setting Device**

The invention relates to a dose setting device for a drug delivery system of the kind wherein a piston rod is successively pressed into a first end of a cylinder ampoule containing a drug

5 to be delivered to press a piston closing said first end of the ampoule into the ampoule so that the drug is pressed out through a delivery member mounted at a second end of the ampoule, the dose setting being provided by rotating a second part of the piston rod in relation to a first part of said piston rod which parts are connected by mating inner and outer threads on the respective parts so that the total length of the piston rod is increased by a distance

10 which is proportional with the extent of the rotation of the parts and by which a point on the second part of the piston rod is moved away from a stop position fixed in relation to a housing so that the set dose is delivered when said point is moved back to the stop position, the first part of the piston rod being guided in the housing so that it can be axially displaced but not rotated, and the second part of the piston rod remote from the piston being mounted so

15 that it can be as well rotated as axially displaced,

From EP 327 910 is known a device by which doses may be set by increasing the total length of a piston rod, which abuts a piston of an ampoule in the device, and a piston rod extension which is through a thread connection coupled to the piston rod. The increase is

20 obtained by rotating the piston rod extension relative to the piston rod by rotating a dose setting member which can be rotated relative to the housing and consequently relative to the piston rod. A connection between the dose setting member and the piston rod extension makes the piston rod extension follow the rotation of the dose setting member. By the resulting increase of the total length of the piston rod and its extension, the outer end of the

25 piston rod extension which were previously flush with the end of the housing is passed out through the end of the housing. The projecting end of the piston rod extension is used as an injection button which can be pressed until it again is flush with the housing. Thereby the piston is pressed into the ampoule a distance corresponding to the set increase of the total length of the piston rod and the piston rod extension. This setting and injection process can

30 be repeated until the ampoule is empty and the piston rod and its extension has reached a maximal length at which time the whole device is disposed of.

Similar dose setting devices are used in durable devices wherein only the ampoule is replaced by a new one when empty. Before a new ampoule can be mounted in the device it is

necessary to screw the two parts of the piston rod together to reduce the total length of said piston rod inclusive its extension to the original length it had before the length was increased through repetitive dose settings. As mentioned the two parts have to be screwed together manually or the thread may be made with a pitch by which the angle of friction for the piston 5 rod material is exceeded so that the parts, if allowed to, will rotate relative to each other and this way be screwed into each other when the parts are pressed axially towards each other. Also the threads may be formed so that they may be drawn out of their mutual engagement when they are pressed towards each other. This axial pressing may be resulted by movement of a part of the housing of the device in order to obtain access to the space accommodating the ampoule.

10 By the device described in EP 327 910 the end of the piston rod rise over the end of the syringe a distance corresponding to the dose set. By small doses this distance may be very small, less than 1 mm. It may be a wish that the injection button has to be moved the same 15 distance independent of the dose which is going to be injected.

A device wherein that wish is met is described in EP 245 312 In this device an injection button with a push rod is reciprocated between fixed end positions. The push rod has a length allowing it just to abut the piston in the ampoule when the injection button is pressed 20 home. If the length of the push rod is increased by a distance corresponding to a set dose when the rod is in its retracted position, it will next time the button is pressed home press the piston into the ampoule a distance corresponding to the elongation provided by the setting of the dose. After the injection the push rod will again be withdrawn from the piston. When the ampoule is empty, the push rod has been elongated to about twice its original length and 25 before a new ampoule can be mounted in the device, the push rod must be screwed back to its original length. A drawback by this device is that the push rod is drawn away from the piston when the injection is finished and the button is no longer pressed, as the piston due to its elasticity and due to the pressure in the ampoule may move backwards in the ampoule whereby as well the just injected dose as the subsequent one are made imprecise.

30 Whereas injection devices so far has been given the shape of a fountain pen, a trend now point towards shorter devices which rather have the shape of a large lighter or a small pack of cigarettes. A reason for this development may be that ampoules with larger content, 3 ml

instead of previously 1,5 ml, demands a pen diameter which makes it impossible to maintain the fountain pen illusion.

Whereas the device according to EP 327 910 could be provided with a flexible piston rod to  
5 adapt it to a short device, the device according to EP 245 312 is not suited for such adapting as the whole piston rod and its extension have to reciprocate in a guide which guides a flexible rod. Whereas the resistance against the movement of a flexible piston rod through a piston rod guide may serve as a barring against backward moving of the piston rod, it will be unacceptable if the piston rod shall be reciprocated as reciprocation is conditioned on a reset  
10 spring which can overcome said resistance. When an injection is made the injection button must be pressed with a force which overcomes as well the resistance in the guide, the force of the spring, and the force necessary to press a liquid out from the ampoule and inject it.

It is an object of the invention to provide a dose setting device which is suited for short de-  
15 vices.

This is obtained by a device as described in the opening of this application which device according to the invention is characterised in that the first part of the piston rod is maintained in abutment with the piston in the cartridge, that the second part of the piston is coupled to a  
20 gear engaging a gear on a dose setting wheel to be rotated when said dose setting wheel is rotated, and that an injection mechanism is provided comprising a push button which can be moved between a projecting position and a pressed home position, and which injection mechanism has elements acting on the second part of the piston rod to press this second part to its stop position when the push button is pressed home.

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In an embodiment of the device according to the invention the threads may be not self locking, the gear engaging the teeth of the dose setting wheel may be locked against unintentional rotation in relation to the housing, and the stop position may be defined by an end position of a surface of a lifter forming a part of the injection mechanism which lifter is reciprocable  
30 between fixed end positions, and said point of the second part of piston rod may be defined as an endpoint at an end of this second part of the piston rod, which endpoint in abutment with said surface forms a pivot about which the second part of the piston rod can rotate when not locked against such rotation.

When the threads connecting the two piston rod parts are not self locking the two parts may be pressed together if they are allowed to rotate in relation to each other. However the first part cannot rotate relative to the housing and as the second part carries a gear engaging the teeth of a toothed dose setting wheel which is again locked against unintentional rotation in

5 relation to the housing, the two parts cannot be rotated relative to each other unless special precautions are taken. A movement of the injection member a constant distance each time an injection button is pressed is ensured by the provision of an injection member which can be reciprocated between fixed end positions. When this member is in its end position defined by the fact that an injection button is pressed home, a surface of the member defines the

10 stop position to which a point of the second part of the piston rod is moved when the injection button is pressed home. The fact that said point is an end point at the outer end of the second part of the piston rod, which endpoint in abutment with said surface forms a pivot about which the second part of the piston rod can rotate when not locked against such rotation, ensures that the piston rod will either transmit axial forces from one end of the piston

15 rod to the other or its parts will rotate so that the two parts are screwed together and the active piston rod is shortened. If the dose setting wheel is voluntarily rotated to set a dose, the two piston rod parts is rotated relative to each other to change the length of the piston rod in accordance with the relative rotation as the rotation of the dose setting wheel is transmitted to the second piston rod part through the gear.

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According to an embodiment of a device according to the invention a connection from a lid covering the ampoule may force the piston rod away from the piston, unlock the dose setting wheel for rotation, and move the second part of the piston rod towards said surface of the lifter to make said end point of this second part abut said surface when the lid is opened.

25 When the first part of the piston rod is drawn away from the piston the nut member will be pressed towards said surface of the lifter and due to the threads being not self locking and due to the second part of the piston rod being freely rotateable the nut member will induce a rotation of said second part of the piston rod and this way be moved to the other end of said second part of the piston rod to be ready for a new series of dose settings and injections.

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In a preferred embodiment of a device according to the invention the threads may be self locking, the stop position may be defined by a beam fixed in the housing which beam may be abutted by a member fixed to the second part of the piston rod, and the nut member may be

so designed that its thread can be coupled free from its engagement with the thread of the second part of the piston rod.

Self locking threads may have a smaller pitch than threads which are not self locking and a 5 lower pitched thread gives a more precise setting of a dose. With self locking threads rotation of the second part of the piston rod may not be relied on when the nut element is going to be moved along this part and the nut element has to be coupled free from its engagement with the thread on the second part of the piston rod to be moved along said second part without this part is rotated. This movement may appropriately be induced by a connection 10 from the lid covering the ampoule when said lid is opened to replace an empty ampoule.

To obtain said coupling free this nut member may have two intersecting bores of which one bore has an inner thread matching the outer thread of the second part of the piston rod and the other bore is smooth and fits slidingly over the thread of the second part of the piston, 15 the nut member being tiltable mounted to the first part of the piston rod so that the threaded bore is concentric with the second part of the piston rod during dose setting and injection and is tilted by said connection which act on the nut member to bring the smooth bore to a position concentric with said second part of the piston during the withdrawal of the piston rod

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In the following the invention will be described in further details with references to the drawing, wherein

Figure 1 shows schematically a syringe with a dose setting mechanism 25 according to the invention in a condition ready for dose setting,

Figure 2 shows the syringe in figure 1 in a condition at the end of an injection,

Figure 3 shows the syringe in figure 1 in a condition where the ampoule is just 30 empty,

Figure 4 shows the syringe in figure 1 in a condition wherein it is opened for replacement of an empty ampoule,

Figure 5 shows schematically a detail of another embodiment of the dose setting mechanism,

5 Figure 6 shows a sectional view along the line VI-VI in figure 5,

Figure 7 shows a sectional view of a tiltable nut member with two bores in a position wherein the threaded bore is concentric with a threaded spindle, and

10 Figure 8 shows the nut member in figure 7 tilted to a position wherein its smooth bore is concentric with the spindle.

In figure 1 an ampoule 1, which is at one end closed by a piston 2 and at the other end closed by a not shown rubber membrane to receive a needle hub 3 with an injection needle 4, is contained in the housing 5 of an injection device, the housing 5 being indicated by a dotted frame.

The piston is acted upon by a flexible piston rod comprising a first flexible part 6 which may e. g. be made as a tightly wound helix of resilient steel. One end of the flexible part 6 acts on 20 the piston 2 through a piston rod shoe 7 whereas the other end which is by a not shown guidance deflected 180° from the first end and is provided with a nut member 8 having an internally threaded opening. An externally threaded spindle 9 is carried in this opening with its thread engaging the internal thread in the opening of the nut member 8. This spindle forms a second part of the piston rod. By rotation of the spindle 9 in the nut member 8 the 25 total length of the piston rod may be changed by varying the part of the second part of the piston rod which lies in extension of the first part 6.

An injection mechanism comprises an injection button 10 at an end of a cogged bar 11, a gear 12, and a lifter 13 having a cogged arm, the coggings of the bar 11 and the coggings of 30 the arm of the lifter 13 being at diametrically opposite sides engaged by the gear 12 which can rotate about a pin fixed the housing whereby a downward movement of the button 10 and the bar 11 is converted to an upward movement of the lifter 13 which can press the outer end of the spindle 9 and thereby press the piston rod in an axial direction so that this piston rod forces the piston 2 further into the ampoule 1. When the device is ready made

ready for injection, a not shown spring will force the press button to the shown projecting position relative to the housing and the lifter to a lowermost position. By injection the button 10 can be pressed home to abutment with the housing 10 where abutting parts 14 are indicated. Not shown stops defines the extreme positions of the parts of the injection mechanism. These extreme positions are indicated by lines 15 and 16 indicating the lowermost and uppermost position, respectively, of a surface 17 on the lifter 13. The distance between the lines 15 and 16 is marked as D.

In figure 1 the outer end point 18 of the spindle 9 lies at the line 16 pressed to this position  
10 by the lifter last time the button 10 was pressed home to abutment with the housing. A dose may now be set by screwing the spindle 9 outwardly in the nut member 8 to make its end point 18 lie between the lines 15 and 16. The size of the dose is defined by the distance between the end point 18 and the line 16 as the endpoint 18 will be moved back to this line when the button 10 is pressed home. The spindle is provided with a gear 19 engaging an  
15 inner toothed on a dose setting drum 20. The drum has a bottom 21 with radial knurls engaging corresponding radial knurls on a disc 22 which is by a spring 23 pressed against the bottom 21 of the drum 20, the knurls being so designed that they with hearable clicks ride over each other each time the drum 20 is rotated a certain angle. e.g. corresponding to an altering of the dose setting by one unit. A dose can be set by rotating the drum 20. This rotation will be transmitted to the spindle which is screwed outwardly in the nut member 8 a distance corresponding to the rotation of the dose setting drum 20. It must be noticed that a too  
20 large dose may be reduced by rotating the drum 20 in the opposite direction.

The rotation of the dose setting drum 20 is sensed electronically and is transmitted to a display whereby the size of the figures on the display is independent of the physical size of the dose setting drum 20 and all other advantages obtained by electronic settings and displays are obtained.

Figure 2 shows the device with the press button 10 pressed home to abutment with the  
30 housing as it appears after a dose has been injected. A not shown lock is provided keeping the button 10 in this position until it is released again, e. g. when the dose setting drum 20 is operated. Also when the apparatus is stored away until the next injection, the press button is maintained in this pressed home position.

Figure 3 shows the device in the same condition as figure 2 but in figure 3 the ampoule is empty and a new element 24 is shown. This element is a piston rod withdrawal element which is connected to a drawer element in which the ampoule is held. Figure 4 shows how the element 24 moves the nut member towards the surface 17 of the lifter when the ampoule

5 1 is drawn out to be changed. As the button is locked in the pressed home position the end tip 18 of the spindle abuts the surface 17 of the lifter which is consequently locked in its shown position. The surface 17 and the tip 18 forms a pivot about which the spindle can rotate if allowed to. When the ampoule drawer is opened the disc 22 is initially drawn away from the bottom 21 of the dose setting drum 20 and this way the dose setting drum 20 is set

10 10 free to rotate. A condition which must be fulfilled is that the engaging threads of the spindle 9 and the nut member 8 are not self locking, i.e. that the angle of inclination for the thread is larger than the angle of friction for the threaded materials.

Figure 5 shows a detail of another embodiment of a dose setting mechanism according to

15 15 the invention. In this embodiment a spindle 25 forming the second part of the piston rod has an axial bore the inner wall of which is provided with a number of longitudinally grooves 26. The spindle 25 is screwed through a nut member 27 at the end of the flexible first part 6 of the piston rod whereby the spindle 25 is divided into a projecting part forming an extension of the first part 6 of the piston rod and a part lying behind the nut member 27. Said part lying

20 20 behind the nut member 27 is guided rotateable and axially displaceable in an opening in a lower beam 29 of an E-shaped construction fixed in the housing. A flange 28 at the end of the spindle 25 limits the axial movement of said spindle and in this way also its rotateability as the spindle 25 will through its engagement with the nut member 27 be longitudinally displaced when rotated until the flange 28 abuts either a middle beam 30 of the E-shaped construction or the lower beam 29 of this construction.

A mainly cylindrical carrier 31 is inserted in the end projecting end of said spindle. The carrier has on its outer cylindrical wall longitudinal splines 37 engaging the longitudinal grooves 26 in the inner wall of the bore in the spindle 25, as it is seen in figure 6, so that rotational

30 30 movement of the carrier 31 is transmitted to the spindle 25 whereas the carrier 31 can be moved axially into the spindle 25. At its outer end surface the carrier 31 is knurled to engage corresponding knurls on a gear element 32 which has teeth engaging an inner toothed rim 33 in a dose setting drum 34. A pin 35 running all the way through axial bores in the gear element 32 and the carrier 31 is at its end projecting through the gear element 32 terminated

by a disc 36 secured to said pin. The pin extends through the bore of the spindle 25 and through a bore in a counting element 38 mounted on a mainly cylindrical stem 39 inserted in the end of the spindle 25 which carries the flange 28. The outer cylindrical wall of the stem is provided with splines 40 engaging the grooves 26 in the spindle 25 so that said stem can

5 be displaced axially but must follow the rotation of the spindle 25. The counting element is placed between the middle beam 30 and an upper beam 41 of the E-shaped construction and has at its outer wall not shown means for activating not shown contacts or sensors fixed in the house to monitor the extent of rotation of the counting member 38 and consequently of the spindle 25 which said counting member is bound to follow. The pin extend through the

10 stem 39, the counting element 38, and the upper beam 41 of the E-shaped construction and is at its upper end provided with a toothed engaging a gear corresponding to 12 in figure 1 - 4 so that the pin carries out the function of a lifter. The elements inserted in the respective ends of the spindle 25, i. e. the carrier 31 and the stem 39, are pressed away from each other by a spring 42 positioned in the bore of the spindle 25. Thereby the knurls of the carrier

15 31 is pressed into engagement with the knurls of the gear element 32 and an end wall of the counting element is pressed into abutment with a surface of the upper beam 41 of the E-shaped construction. Said surface of the upper beam 41 is provided with protrusions 43 which engages mating depressions 44 in the end wall of the counting element. When a dose is set by rotating the dose setting drum 24, the toothed rim 33 of this drum will rotationally

20 drive the gear element 32 from which rotation will be transmitted via the carrier 31 to the spindle 25 unless this spindle is in a position wherein its flange 28 abuts the lower or middle beams 29 or 30 respectively, and the rotation is in a direction which further moves the flange towards the beam in question, in which case the coupling formed by the knurled surfaces of the gear element 32 and the carrier will be released by the knurls sliding over each other as

25 the carrier 31 may be pressed away from the gear element against the force of the spring 42. This way transmission of rotational forces which could be damaging to the device is avoided. By an injection the flange will be moved to abut the middle beam 30 of the E-shaped construction. From this position a dose is set by screwing the flange away from said intermediate beam 30. The size of a set dose is determined by the distance established be-

30 tween the flange 28 and the middle beam 30 and a limit to dose which can be set is determined by the rotation needed to make the flange abut the lower beam 29 of said E-shaped construction.

When the spindle 25 is rotated the stem 39 with the counting element 38 will follow this rotation and the protrusions 43 on the upper beam 41 will slide out of the depressions 44 pressing the counting element 38 away against the force of the spring 42 until the projections meet new depressions to engage. The protrusions and depressions may be provided with a

5 circumferential spacing which makes the number of clicks provided by the successive engagements indicate the size of a dose set.

When a dose is set and the flange thereby is moved away from the intermediate beam 30 of the E-shaped construction, injection may be performed by pressing the injection button of

10 the device to draw the lifter towards the end of the piston rod. The spindle 25 forming the second part of the piston rod is acted upon by a shoulder 45 on the gear element abutting an end surface 46 of the spindle 25. A play between the shoulder 45 and the end surface 46 ensures that the gear element 32 is drawn out of engagement with the the toothed rim 33 before or on an early stage of the injection. This way the dose setting drum is set free so that

15 the size of the dose cannot be influenced during the injection. It must be noticed that the injection button must have a stroke sufficient to allow the lifter to lift the gear element 32 free of the toothed rim 33 and to move the spindle a distance corresponding to the maximal dose which can be set.

20 The engaging threads of the nut member 27 and the spindle 25 are self locking. This allows a smaller pitch of the threads and ensures a more precise dosing. However, precautions must be taken to ensure that the thread of the nut member 27 can be drawn out of engagement with the thread of said spindle so that the nut member can be moved from one end of this spindle to the other without rotating the spindle when the piston rod is drawn back to

25 make room for a new filled ampoule when an empty ampoule is drawn out to be replaced.

Figures 7 and 8 shows a nut 27 member having a first and a second bore the axis of which are intersecting by making an acute angle with each other, the first bore having a diameter corresponding to outer diameter of the threaded piston rod 25 and the second bore having

30 an inner thread mating the outer thread 47 of said piston rod only on parts of this second bore which are not comprised by the first bore.

During dose setting and injection the nut member 27 is in the position shown in figure 7 with its second bore coaxial with the spindle 25 and the thread 48 in this bore engaging the

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thread 47 of said spindle 25. When the spindle is screwed downward in the nut member 27 to set a dose or is lifted upward to inject a set dose it will try to rotated the nut member in the direction of the arrow 49 about a not shown pivot pin at the end of the first part of the piston rod which pivot pin engages a journal 50 arranged on the nut member 27. When the nut member by a piston rod withdrawal element is acted upon at an edge diametrically opposite the pivot pin as indicated by the arrow 51 the nut member 27 is tilted about the pivot pin to bring the first bore to a position wherein it is coaxial with the spindle 25. As the piston rod due to its resistance against withdrawal act on the nut member 27 in the direction of the arrow 52 the nut member 27 will be held in its tilted position wherein it can slide over the top of the thread 47 on the spindle 25 during the withdrawal of the piston rod. In figure 7 and 8 the dotted lines indicate the direction of the bore not coaxial with the spindle.

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## Claims

1. Dose setting device for a drug delivery system of the kind wherein a piston rod is successively pressed into a first end of a cylinder ampoule containing a drug to be delivered to  
5 press a piston closing said first end of the ampoule into the ampoule so that the drug is pressed out through a delivery member mounted at a second end of the ampoule, the dose setting being provided by rotating a first part of the piston rod in relation to a second part of said piston rod which parts are connected by mating inner and outer threads on the respective parts so that the total length of the piston rod is increased by a distance which is proportional with the extent of the rotation of the parts and by which a point on the second part of the piston rod is moved away from a stop position fixed in relation to a housing so that the set dose is delivered when said point is moved back to the stop position, the first part of the piston rod being guided in the housing so that it can be axially displaced but not rotated, and the second part of the piston rod remote from the piston being mounted so that it can be as  
10 well rotated as axially displaced, *characterised in*  
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that the first part of the piston rod is maintained in abutment with the piston in the cartridge,

- 20 that the second part of the piston is coupled to a gear engaging a gear on a dose setting wheel to be rotated when said dose setting wheel is rotated, and

- 25 that an injection mechanism is provided comprising a push button which can be moved between a projecting position and a pressed home position, and which injection mechanism has elements acting on the second part of the piston rod to press this second part to its stop position when the push button is pressed home.

2. Dose setting device according to claim 1, *characterised in that the threads are not self locking,*

- 30 the gear engaging the teeth of the dose setting wheel is locked against unintentional rotation in relation to the housing, and

- 35 the stop position is defined by an end position of a surface of a lifter forming a part of the injection mechanism which lifter is reciprocable between fixed end positions, and said point of the second part of piston rod may be defined as an endpoint at an end of this se-

cond part of the piston rod, which endpoint in abutment with said surface forms a pivot about which the second part of the piston rod can rotate when not locked against such rotation.

- 5 3. A dose setting device according to claim 2, characterised in that a connection from a lid covering the ampoule forces the piston rod away from the piston, unlocks the dose setting wheel for rotation, and moves the second part of the piston rod towards said surface of the lifter to make said end point of this second part abut said surface when the lid is opened.
- 10 4. A dose setting device according to claim 1, characterised in that the threads are self locking, the stop position is defined by a beam fixed in the housing which beam is abutted by a member fixed to the second part of the piston rod, and the nut member is so designed that its thread can be coupled free from its engagement with the thread of the second part of the piston rod.

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5. A device according to claim 4, characterised in that the nut member has two bores forming an angle with each other and of which one bore has an inner thread matching the outer thread of the second part of the piston rod and the other bore is smooth and fits slidingly over the thread of the second part of the piston, the nut member being tiltable mounted to the first part of the piston rod so that the threaded bore is concentric with the second part of the piston rod during dose setting and injection and is tilted when the nut member is acted upon to bring the smooth bore to a position concentric with said second part of the piston.

- 20 6. A device according to claim 5, characterised in that a connection from a lid covering the ampoule forces the piston rod away from the piston by acting on the nut member tilting this member to bring the smooth bore to a position concentric with said second part of the piston during the opening of the lid.

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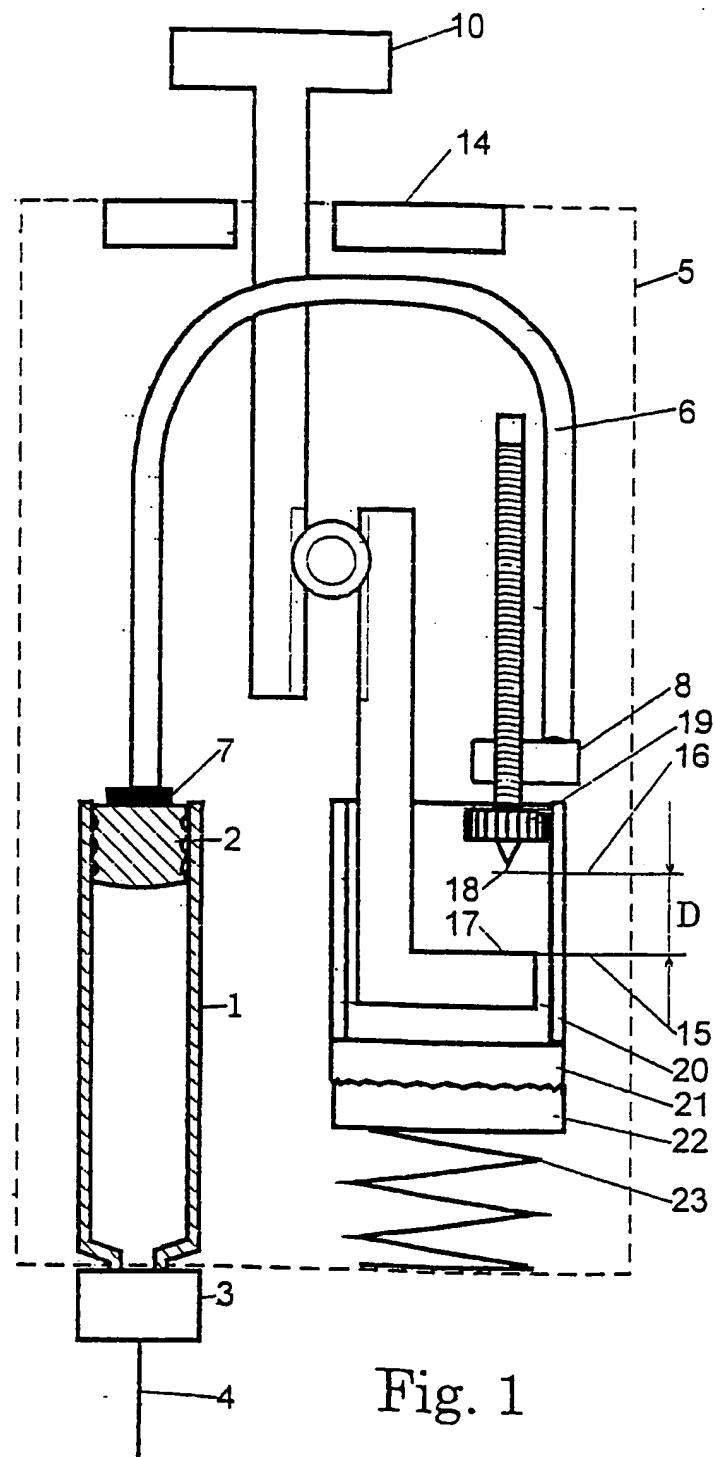


Fig. 1

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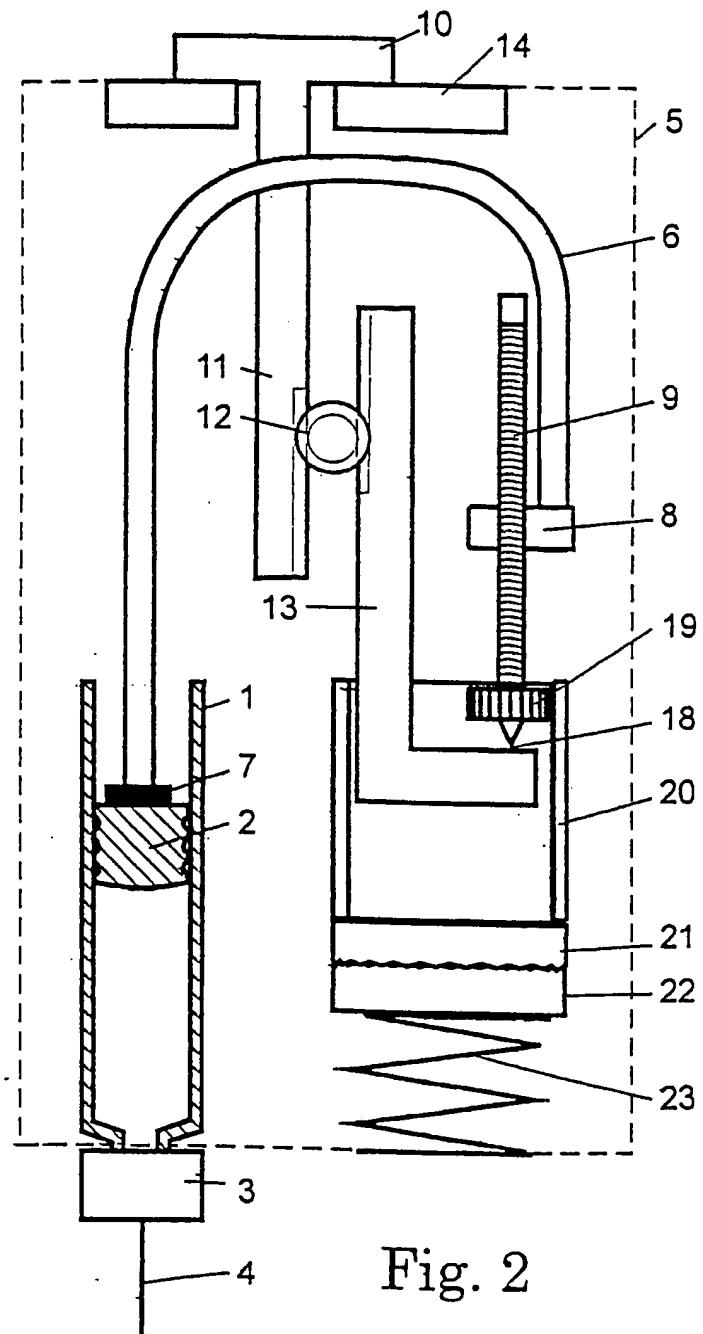
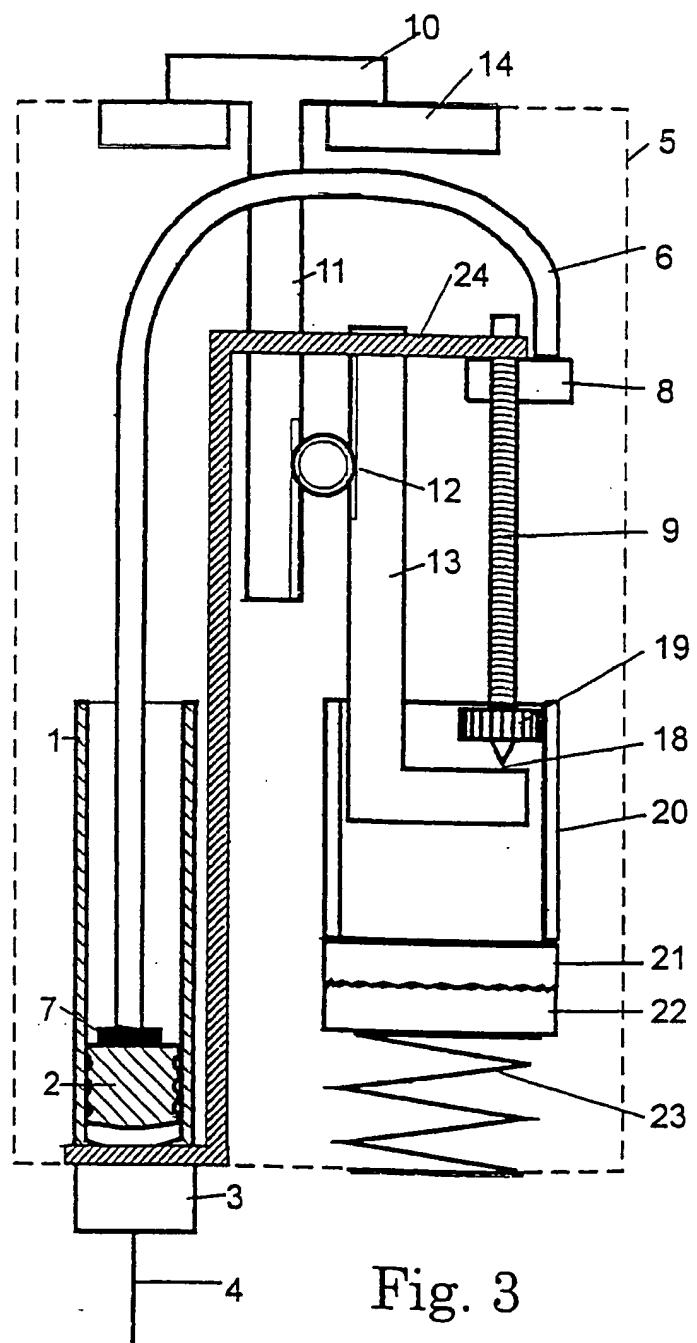


Fig. 2

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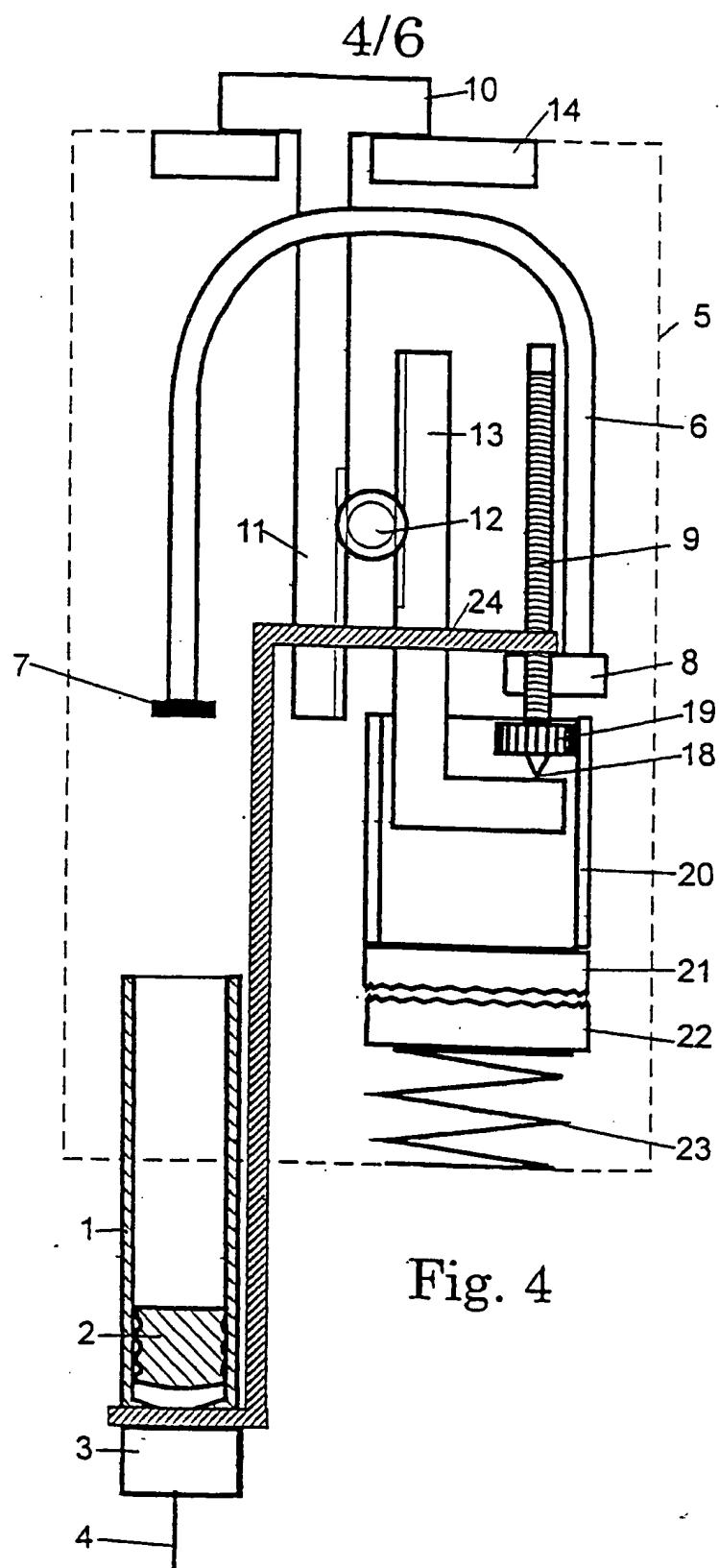


Fig. 4

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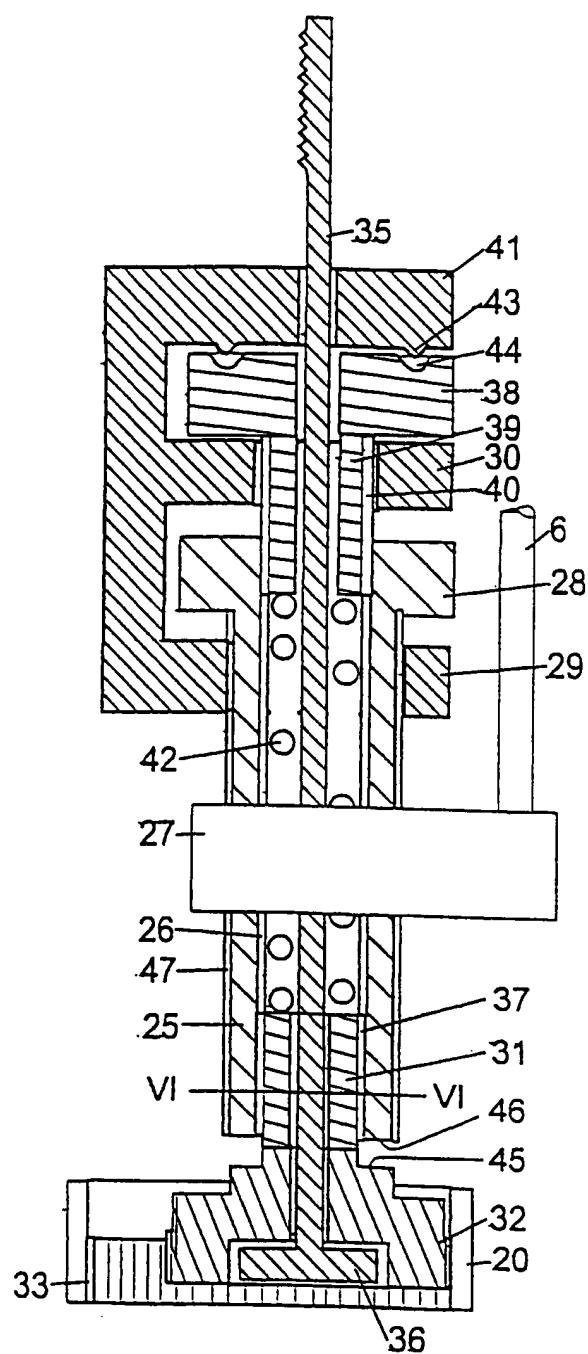


Fig. 5

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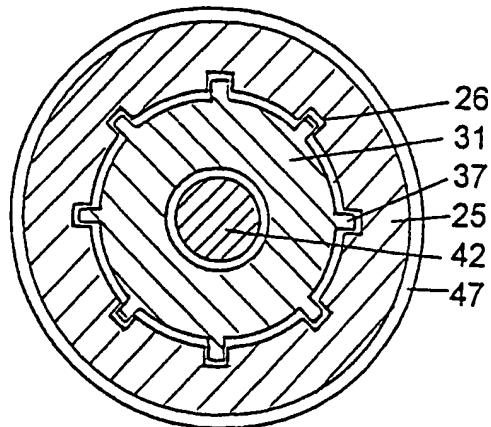


Fig. 6

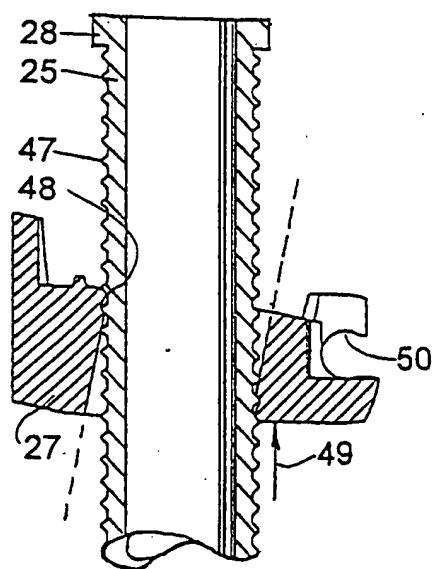


Fig. 7

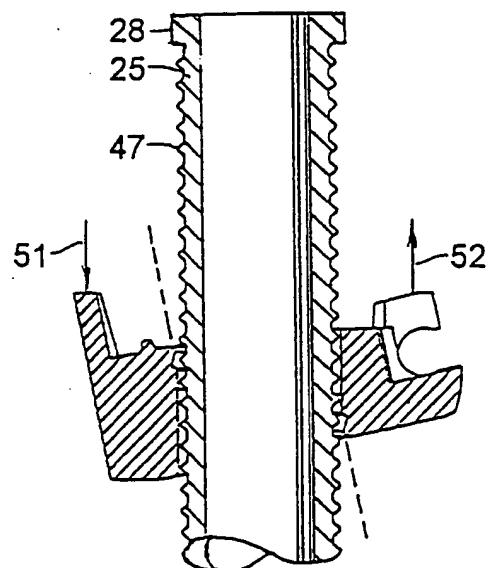


Fig. 8

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 98/00251

## A. CLASSIFICATION OF SUBJECT MATTER

**IPC6: A61M 5/315 // A 61 M 5/24**

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

**IPC6: A61M**

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

**SE,DK,FI,NO classes as above**

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0327910 A2 (D.C.P. AF 1988 A/S), 16 August 1989 (16.08.89)  --	1-6
A	WO 8702895 A1 (DISETRONIC AG), 21 May 1987 (21.05.87)  -----	1-6

<input type="checkbox"/>	Further documents are listed in the continuation of Box C.	<input checked="" type="checkbox"/> See patent family annex.
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* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family
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Date of the actual completion of the international search  <b>21 Sept 1998</b>	Date of mailing of the international search report  <b>25 September 1998 (25.09.98)</b>
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. + 46 8 666 02 86	Authorized officer  <b>Ingrid Falk</b> Telephone No. + 46 8 782 25 00

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

27/07/98

International application No.

PCT/DK 98/00251

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0327910 A2	16/08/89	SE 0327910 T3	
		AU 3066689 A	06/09/89
		CA 1305003 A	14/07/92
		CN 1025719 B	24/08/94
		CN 1035055 A	30/08/89
		CS 8900905 A	16/12/92
		CZ 278561 B	16/03/94
		DK 69288 A	11/08/89
		DK 166948 B	09/08/93
		FI 94930 B,C	15/08/95
		FI 903893 D	00/00/00
		GR 3004398 T	31/03/93
		HR 930507 A	30/04/95
		IE 61515 B	16/11/94
		IL 89189 A	27/02/94
		JP 2726536 B	11/03/98
		JP 3503129 T	18/07/91
		KR 9615612 B	18/11/96
		MX 170604 B	01/09/93
		PT 89669 A,B	04/10/89
		RU 2053798 C	10/02/96
		SI 8910315 A	30/04/97
		SK 278253 B	05/06/96
		US 4973318 A	27/11/90
		WO 8907463 A	24/08/89
<hr/>			
WO 8702895 A1	21/05/87	AU 6541986 A	02/06/87
		BR 8606965 A	03/11/87
		CA 1281956 A	26/03/91
		EP 0245312 A,B	19/11/87
		JP 6013052 B	23/02/94
		JP 63501271 T	19/05/88
		US 4883472 A	28/11/89
<hr/>			